REMARKS

Status of the Claims

Claim 46 has been amended to correct a typographical error. Claims 60-63 are new. Support for the new claims can be found throughout the present specification, for example, at page 5, lines 20-21. Claims 7-11 have been cancelled without prejudice or disclaimer of the subject matter thereof. No new matter has been added.

In the Office Action, claims 1-42 and 53-59 were indicated to be withdrawn, and claims 43-52 and 60-63 are presently under examination.

Rejection of claims under 35 USC 112, first paragraph

In the Office Action, claims 43-52 stand rejected under 35 USC 112, first paragraph, as allegedly lacking enablement. This rejection is traversed.

The Office Action states that the specification "does not reasonably provide enablement for inhibition of tolerance to all narcotic analgesics with all VR1 antagonists." Applicants cannot agree. The Office Action makes conclusory statements regarding what one of ordinary skill would expect without citing any support at all. This does not constitute a proper *prima facie* showing of lack of enablement.

For example, the Office Action asserts that "the skilled artisan would view that the inhibition of addiction of all narcotic analgesics with all VR1 antagonists is highly unlikely."

While it is true that the teachings of the prior art do not describe inhibition of addiction to narcotic analgesics with VR1 antagonists, Applicants point out that enablement is measured against the background of the knowledge of one of skill in the art taken together with the teachings of the present specification. See, e.g., MPEP 2164.01. As discussed in more detail below, the teachings of the specification, taken together with the knowledge of one of ordinary skill in the art, is sufficient to enable the full scope of the claims.

Contrary to the Examiner's assertions, one of ordinary skill would know that existing treatments for narcotic analgesic (opiate/opioid) dependence are generally applicable for all opioids, rather than being limited to particular opioids. See, e.g., the prescribing information for methadone, which shows that this drug, which was approved

by the Food and Drug Administration (FDA) many years ago, is indicated for the treatment of "opioid addiction," not just morphine or heroin addiction. Similarly, the prescribing information for Subutex (buprenorphine) and Suboxone (buprenorphine and naloxone), show that these drugs (which were also in use at the time the present application was filed) are indicated for the treatment of "opioid dependence" generally. Therefore, contrary to the assertions in the Office Action, Applicants contend that one of skill in the art would expect that a method for inhibiting the development of tolerance to, or dependence on, a narcotic analgesic using VR1 antagonists would similarly be applicable to the generic class of narcotic analgesics.

Additionally, the results reported by Kyle et al., U.S. Patent No. 6,974,818 (although not properly citable as prior art against the present application as discussed below), also support Applicants' contention that the presently-claimed methods are fully enabled. For example, Kyle demonstrates (e.g., in Example 6, columns 57-58) that certain VR1 inhibitors can be useful for preventing the development of an addictive disorder. The Examiner's position that the present specification does not provide sufficient enabling support for the claimed methods is without foundation.

Further, the statement that "applicant does not provide any working examples for inhibiting the development of tolerance to all narcotic analgesics with all VR1 antagonists" (Office Action at page 4) is inapt. Applicants are not required to provide working examples showing inhibition of the development of tolerance to all narcotic analgesics with all VR1 antagonists. For example, according to MPEP 2164.02,

> For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation." (emphasis supplied)

In the present case, the specification provides working examples demonstrating that at least three VR1 antagonists (not two as stated in the Office Action) prevent tolerance to repeated opioid dosing and/or reduce side effects due to opioid treatment. As provided in the MPEP, "even in unpredictable arts, a disclosure of every operable species is not required." MPEP 2164.03. All that is required is that one of ordinary skill in the art be able to practice the claimed invention without undue experimentation.

In this case, Applicants have provided ample teachings, including working examples, to permit one of ordinary skill in the art to practice the claimed methods without undue experimentation. Applicants therefore submit that the pending claims fully comply with the requirements of 35 U.S.C. §112.

Rejection of claims under 35 USC 102(e)

In the Office Action, claims 43-45 and 48-50 stand rejected under 35 U.S.C. §102(e), as allegedly anticipated by Kyle et al., U.S. Patent No. 6,974,818 (the "Kyle patent"). This rejection is traversed.

Without agreeing that the disclosure of the Kyle patent would anticipate or render obvious any of the claims of the instant application, Applicants contend that the Kyle patent is not an effective reference against the claims presently under examination.

The Kyle patent issued from an application filed on February 27, 2003. However, the present application claims priority to a provisional patent application filed December 13, 2002, and Applicants urge that this priority application (USSN 60/433,363) fully discloses and enables present claims 43-52 and 60-63. The present invention thus has an effective filing date prior to the date of the application which matured into the Kyle patent. Therefore, the Kyle patent cannot be used in a rejection of the pending claims under 35 U.S.C. §102(e) unless one or more of Kyle's priority applications discloses the allegedly-anticipating subject matter.

While the Examiner points to the Kyle patent as disclosing that "compounds that inhibit vanilloid receptor 1 (VR1) function . . . are administered to animals in need of treatment for addictive disorders," Office Action at page 5, Applicants submit that neither of the Kyle patent's priority applications (USSN 60/411,084 and USSN 60/360,172) discloses the instantly-claimed methods. While the Kyle priority applications disclose that certain compounds are useful for the treatment of pain, neither of the Kyle priority applications teaches or suggests that those compounds would be useful in a method for inhibiting the development of tolerance to a narcotic analgesic in a patient (as claimed in present claim 43) or in a method for inhibiting the development of dependence on a narcotic analgesic in a patient (as claimed in present claim 48). It follows that neither of Kyle's priority applications discloses each element of the present claims. Applicants therefore contend that the Kyle patent cannot be used to

reject the present claims pursuant to 35 U.S.C. §102(e). Reconsideration and withdrawal of the rejection is proper and the same is requested.

Rejection of claims under 35 U.S.C. §103(a)

In the Office Action, claims 46-47 and 51-52 stand rejected under 35 U.S.C. §102(e), as allegedly unpatentable over Kyle et al., U.S. Patent No. 6,974,818, in view of Bakthavatchalam et al., U.S. Patent No. 7,074,799 (the "Bakthavatchalam patent"). This rejection is traversed.

The deficiencies of the Kyle patent have been discussed above. It is Applicants' contention that the Bakthavatchalam patent does not teach or suggest the presently-claimed methods, and, further, does not remedy the deficiencies of the Kyle patent as identified above. Thus, neither the Kyle patent nor the Bakthavatchalam patent, nor the combination thereof, can render obvious the pending claims.

Moreover, Applicants wish to point out that the Bakthavatchalam patent is assigned to Neurogen Corporation, the assignee of record of the present application. The Bakthavatchalam application (now patent) and the present application were, at the time the present invention was made, owned by Neurogen Corporation.

Because the Bakthavatchalam patent and the present application were owned by the same person or subject to an obligation of assignment to the same person at the time the present invention was made, the Bakthavatchalam patent cannot be used in a rejection under 35 U.S.C. 103(a), because the Bakthavatchalam patent qualifies as prior art, if at all, only under 35 U.S.C. 102(e)/(f)/(g). See 35 U.S.C. 103(c)(1) and MPEP 706.02(l)(2).

Reconsideration and withdrawal of the rejection is proper and the same is requested.

CONCLUSION

For at least the foregoing reasons, Applicants contend that the rejections of record should be withdrawn, and that the present application is in condition for allowance. Early and favorable consideration of the application is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 60004 (72021).

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Respectfully submitted,

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